

### **REMARKS**

Claims 1-7, 9-14, 16, 19-25 and 27-42 are now pending in the application. Claims 19, 20 and 31 have been amended and claim 18 has been cancelled in this paper. Applicant respectfully requests special consideration of the claims in light of the Examiner's new reliance on Stark et al. to make obviousness rejections in the outstanding Office Action. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **CLAIM OBJECTIONS**

The Examiner has objected to claims 21-26. Claim 19 as amended includes “a computer-implemented system” which satisfies the objection to claims 21-26 for lack of antecedent basis. Claim 20 as amended includes “computer-implemented system”. Such amendments do not narrow the scope of the claims and are supported in the Specification at paragraphs [0010] – [0014] on pages 4-5; [0048] – [0049] on pages 16-18; and [0077] on pages 32-33.

The Examiner has also objected to claim 31. Applicant has corrected the typographical error by changing the word “deflation” to “inflation” in claim 31. Such an amendment does not narrow the claim scope.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1-7, 9-14, 16, 18-25, 27-30 and 36-42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Zheng et al. (U.S. Pat. No. 5,997,540) in view of

Shabty et al. (U.S. Pat. No. 6,450,981) and Stark et al. (U.S. Pat. No. 6,371,123). This rejection is respectfully traversed.

At the outset, Applicant notes that claim 18 has been cancelled.

The Examiner previously relied on Zheng et al. and Shabty et al. to make obviousness rejections of Applicant's claimed invention but now cites Stark as an additional reference to meet his burden under the obviousness standard. Applicant asserts that:

1. Stark is non-analogous art;
2. Stark teaches away from key aspects of the present invention; and
3. the Examiner does not provide any motivation for combining Stark with the previously cited references.

Citing Stark does not cure the deficiencies of the Examiner's prior obviousness rejections. The combination fails to make a prima facie case for obviousness.

#### **STARK IS NON-ANALOGOUS ART**

Non-analogous art is art that is neither within the inventor's field of endeavor nor reasonably pertinent to the particular problem with which the inventor was involved. *In re Clay*, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992). The present invention is related to electronic counterpulsation devices and seeks to provide solutions to pressure differentials during systole and diastole for patients with circulation problems. The field of endeavor of Stark is strength rehabilitation for orthopedic injuries (column 1, lines 8-12, and column 2, lines 10-14). The problem addressed by the Stark reference is providing physical therapy instruction and sequencing without the need for professional

or medical supervision (column 1, lines 27-37, and column 10, lines 35-45). Strength training and methods of self-administered physical therapy instructions using a computer as a substitute for the hands-on instruction from a medical professional are not pertinent to assisting blood flow using a time- and computer-regulated cuff inflation/deflation based on a patient's heart beat. Stark's computer-recorded instructions (column 8, lines 8-28; and column 9, lines 22-59) for a course of exercise are not analogous to computer-regulated control of a counterpulsation device. Therefore, Stark is non-analogous art.

#### **STARK TEACHES AWAY FROM APPLICANT'S INVENTION**

In addition to being non-analogous art, Stark teaches away from the present invention with respect to medical supervision during the therapy. Under *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984), a prima facie case of obviousness cannot be supported if a modification of the teachings necessary to support the rejection destroys the intent, purpose or function of the reference. As stated, a purpose of the Stark reference is to provide self-guided physical therapy, give the patient control over the therapy administration and to prevent "time-consuming and inefficient contacts" between the treatment professional and the patient (column 10, lines 40-45). In certain embodiments, the patient is directed by pre-recorded sound files and/or visual display on the handheld computer screen (column 9, lines 22-59; and column 10, lines 35-57). The Stark reference goes as far as disclosing embodiments where protocol as prescribed by the health care professional is modified by the computer without the input

or approval of the health care professional (column 10, lines 16-21); and the success of the treatment is determined by the computer (column 10, lines 27-34).

All aspects of the present invention have the intent, purpose and function of providing the medical professional more control in the design and administration of counterpulsation therapy to a patient. To modify the Stark system such that the self-administered therapy components are eliminated and the health care professional has an enhanced role destroys the intent of Stark and is not consistent with Applicant's invention. Because Stark teaches away from Applicant's invention, the Examiner's various obvious rejections including combinations of art including Stark are insufficient for a prima facie showing of obviousness.

#### **NO MOTIVATION TO COMBINE STARK WITH OTHER ART**

Furthermore, the Examiner fails to state and Applicant is not aware of any motivation to combine the references. The Examiner's mere statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993); MPEP §2143.01. See MPEP §2143.01 also citing *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000); and *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999).

Applicant asserts that there is no motivation to combine Zheng, Shabty or Dillon with Stark. Zheng, Shabty and Dillon teach the use of electronic counterpulsation devices under medical supervision to regulate patient blood flow. Stark teaches a device that assists in recovery from an orthopedic injury and eliminates the need for therapist or medical supervision. Those skilled in the medical arts and, in particular, electronic counterpulsation therapy, would not be inclined to reference art directed at a device providing a patient-guided orthopedic therapy regimen for home use.

Even if the references can be properly combined, the combinations fail to teach or suggest Applicant's invention. While Zheng discloses an electronic counterpulsation device and Shabty discloses a "closed loop system" with a computer connected to an electronic counterpulsation device, Stark discloses a computer system for creating and administering physical rehabilitation exercises to a patient with an orthopedic injury. The disclosure of Shabty in light of Zheng and Stark fails to teach or suggest Applicant's electronic counterpulsation apparatus containing a second remote computing device with the ability to communicate over a communications link as claimed in independent claims 1, 10 and 19. Because the combination of Zheng, Shabty and Stark fail to teach or suggest Applicant's invention, the Examiner's obviousness rejection of these claims is improper. The obviousness rejection is similarly improper for dependent claims 2-7, 9, 11-14, 16 and 19-25, which are at least as limited as the independent claims for the reasons stated above. Therefore, reconsideration and withdrawal of these rejections are respectfully requested.

Claims 31-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shabty et al. (U.S. Pat. No. 6,450,981) in view of Zheng et al. (U.S. Pat. No.

5,997,540), Dillon (U.S. Pat. No. 5,514,079) and Stark (U.S. Pat. No. 6,371,123). This rejection is respectfully traversed.

As stated above, the combination of Zheng and Shabty fail to disclose Applicant's invention. Applicant respectfully points out that the Examiner admits in the Office Action at paragraph 12 that the citation to Stark is misplaced because the Stark reference discloses neither a counterpulsation system nor a timing bar for counterpulsation use or any orthopedic use. The addition of the Dillon reference, which teaches the use of EKG sensing devices to control cuff inflation and deflation, still fails to disclose Applicant's computer-implemented system for treating a patient and recording patient information containing a remote computer connected to the local computer over a communications link, as more fully discussed above. Because Dillon fails to cure the deficiencies of the prior art as discussed above and the combination of Zheng, Shabty, Dillon and Stark fails to teach or suggest Applicant's invention, the Examiner's obviousness rejection is improper. Therefore, reconsideration and withdrawal of these rejections is respectfully requested.


#### **CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the

Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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